

Patent/Docket No. 23100.40

Customer No. 27683

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:
McANALLEY, B.

Serial No.: 10/001,439

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For: DIETARY SUPPLEMENT
COMPOSITIONS

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Confirmation No. 2421

Group Art Unit: 1654

Examiner: Coe, Susan D.

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MAIL STOP APPEAL BRIEF - PATENTS

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REPLY BRIEF

This Reply Brief is submitted in response to the Examiner's Answer mailed January 12, 2006. As the two-month date for reply falls on a Sunday, this Reply Brief is timely filed on the following Monday, March 13, 2006.

- (1) Real Party in Interest - Same
- (2) Related Appeals and Interferences - Same
- (3) Status of Claims - Same
- (4) Status of Amendments After Final - Same
- (5) Summary of Claimed Subject Matter - Same
- (6) Grounds of Rejection To Be Reviewed On Appeal - Same
- (7) Claim Appendix - Same
- (8) Evidence Relied Upon - Same

REPLY

For the following reasons, it is clear that the Examiner's Answer fails to establish a case for obviousness against claims 1, 8-17 and 19 based on Donzis 5,576,015 ('015); Paul 5,531,989 ('989); and Plaut WO 97/05884 ('884). Applicant's arguments in the Appeal Brief are incorporated herein by reference in their entirety.

The Examiner's Answer and Grounds for Rejection

The Examiner's Answer fails to support a rejection of the claims based on a combination of three references because they still do not teach, suggest or motivate the combination of the present invention.

Analyzing the patentability of claims under 35 U.S.C. § 103(a) requires casting the mind back to the time of invention to: (1) consider the thinking of one of ordinary skill in the art; (2) guided only by the prior art references; and (3) the accepted wisdom in the field. *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). To do otherwise causes the examiner "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

It is well-established that most inventions arise from a combination of old elements, therefore, it is not only possible but even common to find every element in the prior art. See *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998). However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention; there must be a motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *Id.*

The Court of Appeals for the Federal Circuit has clearly stated that "[b]road conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. When relying on numerous references or a modification of prior art, "it is incumbent upon the examiner to identify some suggestion to combine references or make the modification." *Id.* An examiner can satisfy its burden of obviousness in light of a combination "only by showing some objective teaching [leading to the

combination]”); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion “essential” to avoid hindsight).

Unfortunately, the Examiner’s Answer falls into the hindsight trap with art that does not support the contentions or lead to a reasonable expectation of success.

The Examiner’s Answer dives head-first into the trap of impermissible hindsight by extracting terms from the present invention (viz., “essential saccharides”) and imputing that term to the art cited. None of the references include the term “essential saccharides.” Next, the Examiner uses the present specification and claims as a template to gather the individual parts to reach the present invention.

Let’s explore how. It is alleged in the Examiner’s Answer that each of the three references is directed to immune stimulation and *ipso facto* the skilled artisan would combine them. The problem is that none of the references teach, direct, suggest, motivate or argue that the skilled artisan could combine their components to achieve the present invention, viz., the novel dietary supplement of the present invention. A thorough analysis of the actual substance of the references shows that any such combination is, at best, superficial, and as shown below, incorrect.

The ‘989 Reference Fails to Link the Element with an Immune Response

U.S. Patent 5,531,989 fails as prior art because it fails to show that the element used to reject the claims has the so-called immune response.

According to the Examiner’s Answer:

US ‘989 teaches that a composition comprising lactoferrin and fiber enhances the patients [sic] immune system and treats diseases caused by bacteria, viruses, fungi, and parasites (see column 3, lines 32-50). US ‘989 teaches that the fiber is from citrus pectin and from guar gum. **Guar gum is specifically claimed by applicant in claim 19 as containing “essential saccharides.”** (Original in bold). *Thus, this reference shows that it was known in the art at the time of the invention that compositions containing lactoferrin, “essential saccharides,” and citrus pectin enhance the immune system and also treat diseases caused by bacterial and viral infection.* (Examiner’s Answer, Page 3). (Emphasis added after the original bold portion).

Let us explore the substance of the rejection. The portion of ‘989 reference cited in the Examiner’s Answer is reproduced below:

It is an object of the present invention to provide a composition for use as a dietary supplement that benefits human gastrointestinal health when administered orally.

It is also an object of the invention to provide a composition for use as a dietary supplement that, when ingested, is effective for treating ailments due to gastrointestinal pathogens such as bacteria, viruses, fungi, or protozoa.

It is another object of the invention to provide a composition for use as a dietary supplement that, when ingested, results in decreased serum cholesterol, triglycerides, and phospholipids and an increased HDL to LDL ratio.

It is still another object of the invention to provide a composition for use as a dietary supplement that aids in preventing deleterious effects of oxygen free radicals.

It is yet another object of the invention to provide a composition for use as a dietary supplement that bolsters the body's immune system and the natural non-immune system, the LP system. (column 3, lines 32-50).

Careful analysis and review of what the '989 reference actually teaches demonstrates that the Examiner's Answer is factually incorrect. The only portion of the composition that causes an immune response in the '989 reference are the immunoglobulins. That is it.

Let's focus on the key element of the '989 reference that were used for the impermissible hindsight reconstruction. The Examiner's Answer states that "guar gum is specifically claimed by the applicant in claim 19 as containing "essential saccharides," and that "lactoferrin, "essential saccharides," and citrus pectin enhance the immune system and also treat diseases caused by bacterial and viral infection." (Examiner's Answer, page 3). In other words, the Examiner's Answer states unequivocally that the lactoferrin, "essential saccharides," and citrus pectin enhance a patient's immune system.

In the '989 specification, the terms citrus pectin, guar gum and "fructo-oligosaccharide" are described as follows:

Therefore, at least the following positive effects are obtained by addition of inulin and/or fructo-oligosaccharides (FOS) to a composition for use as a dietary supplement according to the present invention: reduction of intestinal disorders, enhancement of a balanced intestinal microflora, and remediation of constipation. (Col. 7, ll. 4-9).

In other words, the portion of the art cited that teaches use of the fructo-oligosaccharides (FOS) teaches: reduction of intestinal disorders, enhanced intestinal flora and remediation of constipation, **NOT**, the immune effect argued in the Examiner's Answer. What the skilled artisan would learn from the '989 specification is that the fiber (in the form of FOS) is good for intestinal health and preventing oxidative damage:

Pectin and guar gum have several beneficial effects on the gastrointestinal tract, such as **maintaining the morphology of intestinal villi, increasing lipase activity** in the small bowel, **delaying gastric emptying time, increasing intestinal transit time, and promoting increased fecal production** of short chain fatty acids. It is believed that pectin and guar gum in the diet **lower blood glucose and serum cholesterol levels**, B. Flourie et al., The Effect of Pectin on Jejunal Glucose Absorption and Unstirred Layer Thickness in Normal Man, 25 Gut 1936 (1984). (Col. 7, ll. 31-51) (Emphasis added). ...

Moreover, **pectin and guar gum are also thought to prevent oxidative damage** in the gastrointestinal tract. Oxygen free radicals are involved in many deleterious processes including aging, inflammation, and some disease processes. The gastrointestinal mucosa is exposed to oxidants produced within the lumen and in the epithelial cells. Potential sources of luminal oxidants include ingested food, catalase-negative bacteria, and cigarette smoke and other pollutants. (Col. 7, ll. 52-59). (Emphasis added).

A detailed look at the teachings (and the only scientific interpretation of the teachings of the '989 specification) demonstrates that the FOS serve as a mere carrier. The '989 reference teaches that this carrier is used to "ferry" the portion of the reference that causes the immune response, viz., immunoglobulins, into the digestive tract.

The Examiner's Answer states, "this reference shows that it was known in the art at the time of the invention that compositions containing lactoferrin, "essential saccharides," and citrus pectin enhance the immune system and also treat diseases caused by bacterial and viral infection." Nothing in the '989 reference supports that statement. In fact, the '989 reference teaches the opposite in the following two passages:

The immunoglobulin composition **can also include a carrier**. A preferred carrier comprises at least one member selected from the group consisting of a **carbohydrate and a lipid, wherein the carbohydrate is capable of being an energy source for a beneficial human intestinal microorganism** and the lipid aids in reconstitution of the immunoglobulin composition. (Col. 4, ll. 31 - 37). (Emphasis added) ...

As used herein, "immunoglobulin composition" means a composition comprising an effective amount of immunologically active immunoglobulins. Preferably, these are present as concentrated immunologically active immunoglobulins. One such immunoglobulin composition is sold under the trademark "PROBIOPLEX" by Metagenics, Inc. (San Clemente, Calif.). PROBIOPLEX contains (1) about 55-60 parts by weight of an immunoglobulin concentrate from bovine whey wherein at least about 7% by weight of the total solids in the concentrate is immunologically active immunoglobulins, (2) about 35-40 parts by weight of a mixture of carbohydrates including rice maltodextrin and lactose, and (3) about 5-10 parts by weight of lipid including lecithin. Thus, at least about 3.6% by weight of the total PROBIOPLEX composition comprises immunologically active immunoglobulins. **The carbohydrates and lipids function as inert carriers for the immunoglobulins**. (Col. 5, ll. 14 - 28). (Emphasis added).

Clearly, the actual teaching of the '989 reference is that the carbohydrates are inert carriers that may be used to feed intestinal microorganisms. An "inert carrier" can not have the effects that serve as the basis for the Examiner's Answer. The immunoglobulins are the immunologically active portion of the composition, **NOT** the "inert carriers." Therefore, the art cited fails both scientifically and legally. It can neither provide the missing element, nor can it provide a legal link sufficient to reach the other references.

To the contrary, the '989 reference teaches that the immunoglobulin is what enhances the immune system and also treats diseases caused by bacterial and viral infection, not the citrus pectin and guar gum. Any interpretation to the contrary would be against the explicit teachings of the '989 reference.

In conclusion, the Examiner's Answer mischaracterizes the art and fails because:

- (1) the '989 reference teaches that the immunoglobulins serve to enhance immunity **NOT** the citrus pectin or the guar gum,
- (2) the carbohydrates serve as mere inert carriers;
- (2) the combination is improper because nothing in the '989 reference teaches the combination with a beta-glucan or colostrum (evidence of hindsight reconstruction); and
- (3) the present application teaches the concept of "essential saccharides" not the '989 reference (clear evidence of hindsight reconstruction).

Simply stated, the '989 reference has no clothes.

Accordingly, it is clear that the rejection of claims 1, 8, 17 and 19 under 35 U.S.C. §103(a) over the combination of Donzis '015, Paul '989 and Plaut '884 fails, is improper and should be withdrawn because the '989 reference provides neither a reasonable expectation of success, nor a teaching, suggestion or motivation to combine with the other components.

The '884 Reference Also Fails the Reasonable Expectation of Success Test.

There is also no reasonable expectation that a modification or combination of Donzis '015, Paul '989 and Plaut '884 would successfully achieve the subject matter of claims 1, 8-17 and 19.

The Examiner's Answer states that Plaut '884, "teaches that lactoferrin and colostrum strengthen the immune system (see page 3, second paragraph)." Below please find the text of the cited paragraph:

Accordingly, the invention features, in one aspect, an infant formula which includes pasteurized milk (e.g., colostrum), active lactoferrin (e.g., nonpasteurized lactoferrin), **and an antibody which specifically binds** (i.e., inhibits the proteolytic activity of) either an IgA protease or an IgA protease precursor, or both an IgA protease and an IgA protease precursor. (page 3, second paragraph). (Emphasis added).

Nothing in this paragraph supports the statement in the Examiner's Answer. In fact, the cited portion indicates that the taught formulation has an additional antibody added to the compositions, viz., "and an antibody which specifically binds (i.e., inhibits the proteolytic activity of) either an IgA protease or an IgA protease precursor." (page 3, second paragraph).

Next, the Examiner's Answer states, "[i]n addition, this composition is taught to treat disease caused by bacterial and viral infections (see page 2, last paragraph)." Below is the text of that portion of the '844 reference:

Certain infant formulas have been designed to protect the infants that drink the formula against bacterial and rotavirus infections. Modification of infant formula typically involves immunizing a pregnant cow with certain bacteria or their toxins, and then extracting the desired antibody from the colostrum (the first milk after calving) for addition to formula products. Such antibodies are known to protect children against infection by several intestinal pathogens including enterotoxigenic E. coli, Vibrio cholerae, and rotaviruses.

Applicant agrees with that portion of the Examiner's Answer that cites to the Background of the Invention for the proposition that animal colostrum from an immunized animal increases the amount of desired anti-bacterial and other antibodies. What '884 does not teach, nor motivate, nor suggest is the use of the colostrum in a dietary supplement that also includes a complex of essential saccharides, lactoferrin or citrus pectin.

The cited art is directed to an infant formula (which are well known) that has been enhanced with "an antibody which specifically binds (i.e., inhibits the proteolytic activity of) either an IgA protease or an IgA protease precursor, or both an IgA protease and an IgA protease precursor." That is, the infant formula is already an immunoglobulin containing formula to which additional IgA protease-specific antibodies are added to enhance the immune response. Nothing in the reference teaches that the skilled artisan combine the reference with any one of the remaining components, viz., a complex of essential saccharides, lactoferrin, guar gum or citrus pectin.

Nothing in the reference teaches that those items could be included with the present invention, nor the usefulness of their addition.

Without a clear teaching, suggestion or motivation for the modification or combination of Donzis '015, Paul '989 or Plaut '884, the second criterion of a prima facie case of obviousness is not been met because there could be no reasonable expectation of success.

The '015 Reference

The Examiner's Answer cites to a portion of the '015 reference that fails to support the rejection in the Examiner's argument. The Examiner's Answer rejects the present claims to a dietary supplement by arguing that "US'015 teaches that beta-glucan from yeast cell walls enhances host immune resistance to diseases caused by bacterial and viral infection (see column 1, lines 20-38)."

Below please find the actual text of that portion of the reference cited by the Examiner:

Glucan extracted from yeast cell walls is known to be a potent stimulator of the immune system. Studies have indicated that **parenteral administration** of glucan significantly modifies host resistance to a wide variety of infectious disease induced by bacterial, fungal, viral, and parasitic organisms (DeLuzio, Trends in Pharmacological Science, 4:344-347, 1983). Glucan has also been shown to have potent antitumor activity (DeLuzio et al., Advances and Experimental Medicine and Biology, 21A:269-290, 1979). The mechanism by which glucan exerts its beneficial effects is believed to be by interaction with specific glucan receptors located on the macrophage cells. (Czop, Pathology & Immunopathology Res., 5:286-296, 1986). The above studies teach, however, a toxic effect from the parenteral administration of yeast extract beta (1-3) glucan that appears to render the product unusable. This toxic effect is believed to derive from the particulate nature of the product, and has lead to a search for an effective water soluble yeast glucan extract. (Col. 1, ll. 20-38). (Emphasis added).

The skilled artisan will recognize instantly that something that is provided parenterally is not provided to a subject through the digestive tract! Therefore, the citation fails to support the rejection because something provided parenterally is not provided via the digestive tract, as is the case with the present invention. Parenterally, is defined as follows:

Merriam-Webster Online Dictionary (<http://www.m-w.com/dictionary/parenteral>)

Parenteral ...

: situated or occurring outside the intestine; especially : introduced otherwise than by way of the intestines.

Therefore, the portion of the '015 reference cited teaches parenteral administration, not a dietary supplement, which, in fact, is the opposite of the present invention.

Despite this clear error in the Examiner's Answer, the Applicant acknowledges that the actual reference teaches dermatological and nutritional uses of a beta-glucan. However, despite the teaching that beta-glucan enhances phagocytosis of macrophages (a non-specific activation of immune cells, not an antigen-specific or classical "immune" response) there is still nothing in the '015 reference that would lead a skilled artisan to the combination of the one ingredient, beta-glucan, with the other components of the present invention.

Therefore, there is no suggestion or motivation to modify any of Donzis '015, Paul '989 or Plaut '884 to include all of the limitations of any of claims 1, 8-17 and 19 to lead the skilled artisan to a composition that includes each of β -glucan, colostrum, lactoferrin and citrus pectin, as well as a complex of essential saccharides.

Improper Combination or Modification of Donzis '015, Paul '989 and Plaut '884.

None of Donzis '015, Paul '989 or Plaut '884 recognize the myriad of beneficial effects on the health and well-being of a recipient that are realized upon the dietary supplementation and absorption of the combination of β -glucan, colostrum, lactoferrin, citrus pectin and a complex of essential saccharides.

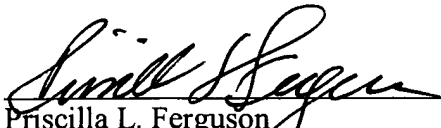
Conclusion.

In view of the above, Applicant submits that the Examiner's Answer fails because the references cited: Donzis '015, Paul '989 and Plaut '884, are improperly combined and not likely to lead to a reasonable expectation of success. Accordingly, it is clear that the rejection of claims 1, 8 17 and 19 under 35 U.S.C. §103(a) over the combination of Donzis '015, Paul '989 and Plaut '884 is improper and should be withdrawn and the claims allowed.

For all of the foregoing reasons, claims 1, 8-17 and 19 are in condition for allowance. Favorable reconsideration of claims 1, 8-17 and 19 is respectfully requested.

Respectfully submitted,

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CLAIMS APPENDIX - Same

EVIDENCE APPENDIX - NONE.

RELATED PROCEEDINGS APPENDIX - NONE.

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